



05-19-06

AF/1654
JFM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE: BATES, James N., et al.)
) APPEAL NO. _____
SERIAL NO: 09/879,710)
)
FOR: S-METHYLCYSTEINE, S-ETHYL-)
CYSTEINE, AND RELATED)
S-ALKYLTHIOLS AS ANTAGO-) SUPPLEMENTAL REPLY BRIEF
NISTS TO THE EFFECTS OF S-)
NITROSOTHIOLS AND NITRIC)
OXIDE)
)
FILED: June 12, 2001)
)
GROUP ART UNIT: 1654)

To the Commissioner of Patents and Trademarks
Mail Stop PATENT APPEAL,
P. O. Box 1450,
Alexandria, VA 22313-1450

Dear Sirs:

Appellants respectfully requests that the following Reply Brief be entered into the record. It addresses new rejections and arguments set forth in the Examiner's Supplemental Answer. Its entry is therefore proper under 37 C.F.R. § 1.193.

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CERTIFICATE OF MAILING BY EXPRESS MAIL

I hereby certify that this document and the documents referred to as enclosed therein are being deposited with the U. S. Postal Service in an envelope as "Express Mail Post Office to Addressee" addressed to: Commissioner of Patents, P. O. Box 1450, Alexandria, VA 22313-1450, prior to 5:00 p.m. on 18 day of May, 2006.

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I. **ARGUMENT**

A. **The Meisner Composition Would Not Inherently Inhibit Nitric Oxide Synthesis**

Claims 2, 3, 8, and 10 were rejected under 35 U.S.C. 102(b) as being anticipated by Meisner. It is the Examiner's position that Meisner's composition containing S-methylcysteine anticipates the claims on the basis that administration of the Meisner composition would have inherently inhibited nitric oxide synthesis "since the steps of the process (Meisner and the instant application) are the same." (Examiner's Supplemental Answer, p. 4). This position is simply incorrect, both scientifically and legally.

It is undisputed that the Meisner composition includes "a precursor or stimulant of epinephrine or norepinephrine selected from tyrosine and phenylalanine." (See e.g. claim 1). Tyrosine and phenylalanine are precursors of the neurotransmitters catecholamines, which include tyramine, dopamine, epinephrine, and norepinephrine. It is well established that catecholamines enhance inducible nitric oxide synthase-induced nitric oxide biosynthesis. (See e.g.

[http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=15976236&dopt=Abstract.\)](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=15976236&dopt=Abstract.)

Thus, contrary to the Examiner's assertion, the Meisner compositions would not inherently inhibit nitric oxide synthesis, since they contain at least one compound that enhances nitric oxide synthesis. Thus, the Meisner composition does not meet the limitations of claims 2, 3, 8, and 10. The Examiner's rejection under 35 U.S.C. § 102(b) must therefore be reversed.

B. Rejection Under 35 U.S.C. § 103(a), Meisner, Taken with Joullie et al. and Chemical Abstracts Registry

Claims 2-8 and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Meisner taken with Joullie et al. and Chemical Abstracts Registry file print.

The Examiner refutes Appellants' position that the vasoconstricting agents required by Meisner would "materially affect the basic and novel characteristic(s)" of the claimed invention, and therefore are excluded from the scope of Appellants' claims. In this respect, the Examiner argues that, "Appellants never explained on the record how their method's composition did not contain elements which materially changed the fundamental characteristics of the invention only that Meisner contained other elements and therefore their claims were excluded by "consisting essentially of." (Examiner's Brief, p. 6). This argument is not understood, however, since Appellants' specification is indisputably part of the record, and certainly does explain how the Meisner elements, i.e. vasoconstrictors, would fundamentally change the characteristics of the claimed invention. In this regard, the specification explicitly states that:

Current treatment options for hypotension or shock from such conditions such as septic shock, toxic shock syndrome, spinal cord injury, effects of anesthetics, and anaphylaxis, etc. are limited to vasoconstricting agents that may have deleterious side effects that limit their effective therapeutic usage.

(Spec. p. 2, second paragraph). Thus, Appellants already explicitly stated, on the record, that vasoconstricting agents are unsuitable for use in their treatment methods, and are therefore outside of the scope of claim 10 and claims 2-8 depending therefrom.

Meisner, of course, requires the presence of a vasoconstricting agent (Col. 2, lines 67-68 to Col. 3, lines 1-6), namely a precursor or stimulant of epinephrine or nor-epinephrine production, in its method. Since such agents have been shown to materially change the

fundamental characteristics of the invention, vasoconstricting agents must be excluded from the scope of Appellants' "consisting essentially of" claims.

The Examiner next states that Appellants' argument that Meisner requires the presence of a vasoconstrictor is without merit, because Meisner does not teach the use of the vasoconstricting agents epinephrine and nor-epinephrine *per se*, but precursors of the same. Appellants fail to see the distinction. Meisner notes that tyrosine and phenylalanine are precursors or stimulants of epinephrine or nor-epinephrine production. (Col. 3, lines 1-3). Whether the compounds disclosed by Meisner directly provide vasoconstriction, from compounds that are direct vasoconstrictors, or stimulate vasoconstrictor production, the end result is the same.

Finally, the Examiner states that, "the claims never require the patient to suffer from anything, thus the argument that the invention is aimed at avoiding the side effects of vasoconstrictors is without merit since anyone according to the claims can be administered this composition claimed no matter what their need is." (Examiner's Supplemental Answer, p. 7). While difficult to understand exactly what the Examiner is attempting to argue here, it seems that the Examiner is requiring Appellants' claims to specifically state that the method is used to "avoid the side effects of vasoconstrictors." Such a limitation would be redundant and pointless since the intended use or purpose of the compound described in the specification is cited for interpreting the scope of the "consisting essentially of" transition phrase in claim 1. Again, a cited objective of the invention is to avoid the side effects of vasoconstrictors, thereby precluding the use of such compounds in Appellants' claimed method since such compounds would "materially affect the basic and novel characteristic(s) of the claimed invention." MPEP § 2111.03.

The addition of the secondary references of Joullie et al. and Chemical Abstracts do not alleviate the missing teachings of the primary reference. The Examiner argues that, "it would have been well within the purview of the skilled artisan to inject the S-methylcysteine composition of Meisner into a patient since, as taught by Joullie, it is well known to inject S-methyl cysteine for therapeutic purposes." (Examiner's Supp. Brief, p. 5). It has already been established, however, that Meisner does not teach the administration of a composition that inhibits nitric oxide overproduction since it requires the co-administration of an agent that enhances nitric oxide production. Further, the evidence demonstrates that it is not obvious in view of Meisner to inject an S-methylcysteine composition into a patient without the co-administration of a vasoconstricting agent. Thus, the addition of Joullie and Chemical Abstracts as secondary references to the primary reference do not overcome the deficiencies in the Examiner's case for obviousness.

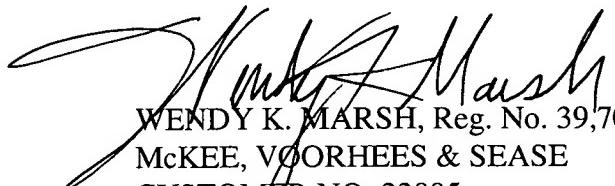
Since Meisner, even in view of the secondary references, does not teach or suggest the use of a composition that does not include a vasoconstricting agents, claims 2-8 and 10 are not rendered obvious by the cited references. The rejection of claims 2-8 and 10 under 35 U.S.C. § 103 must therefore be reversed.

II. CONCLUSION

For the above-stated reasons, and for the reasons set forth in Appellants' appeal brief, Appellants respectfully request reversal of the decision of the Examiner, and allowance of the application.

It is not believed a fee is due with this brief. If a fee is due, please consider this a request to debit or credit Deposit Account No. 26-0084 accordingly.

Respectfully submitted,



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